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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,523	11/21/2003	Kenneth J. Rothschild	AMBER-08501	3365

7590
MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, CA 94105

EXAMINER

JOIKE, MICHELE K

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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06/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,523

Applicant(s)

ROTHSCHILD ET AL.

Examiner

Michele K. Joike

Art Unit

1636

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9,11-13 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,11-13 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2010 has been entered.

Claims 1, 9, 11-13 and 38-41 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed January 19, 2010 that is not addressed in this action has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 9, 11-12 and 38-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (US Patent No. 6,207,370) in view of Garvin et al (US Patent No. 6,329,180; IDS Ref. 1) and in further view of Nakajima et al and Hosfield et al.

Claims 1, 9, 11-13 and 38-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (cited above) in view of Garvin et al (cited above) and in view of Nakajima et al and Hosfield et al (cited above) as applied to claims 1, 9, 11-12 and 38-41 above, and further in view of Elion et al (*Current Protocols in Molecular Biology*, Unit 3.17, pages 3.17.1-3.17.10, 1993).

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicants' arguments filed March 23, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that Nakajima et al merely disclose a multiple epitope tag using primers. The forward and reverse primers are simply c-myc domains that partially hybridize to each other and serve as their own template. It does not address the problem solved by the three different tags of the present invention, and is therefore non-analogous art.

Hosfield et al deals with epitope markers in vectors, not primers. Hosfield et al is also non-analogous art.

Furthermore, the Examiner is using hindsight reconstruction. Applicants argue that what one does with the amplified nucleic acid sequence is the question, and the Examiner is ignoring this.

These arguments are not found persuasive for the following reasons.

Little et al teach two primers. One primer has the T7 promoter, a RBS, a start codon and an epitope marker. The second primer had a stop codon and a second epitope marker. Garvin et al teach two primers, each with different primers. Nakajima et al is added to teach that more than one epitope marker can exist in a primer. In other words, primers with multiple epitopes were known in the art. Hosfield et al teach do teach a vector with different multiple epitopes. This reference was not used to teach primers, which Little et al, Garvin et al and Nakajima et al already teach, but to teach the different epitope markers can exist in the same nucleic acid molecule together and be functional when expressed. Nakajima et al teach that multiple-epitope tags increase sensitivity of detection by antibodies, and Hosfield et al teach that epitope tagging is a convenient technique in which a known peptide epitope is fused to a target protein of interest, allowing expression of the fusion protein to be monitored using a tag-specific antibody.

In response to applicant's argument that Nakajima et al and Hosfield et al are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Nakajima et al is in the field of endeavor and is reasonably pertinent. Nakajima et al teach primers with multiple epitope markers, which is part of what applicants are claiming. Hosfield et al is also pertinent as it teaches the use of different epitope markers. Neither reference is non-analogous art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, Applicants are claiming a product, a reaction mixture containing two primers, not a method of using the primers. The intended use of the primers is not relevant.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Primary Examiner, Art Unit 1636

Michele K. Joike
Primary Examiner
Art Unit 1636